

REMARKS

Favorable reconsideration is respectfully requested in light of the above amendments and the following comments. The specification has been amended for clarity. Claim 1 has been amended for clarity, as well as to include the limitations of claim 3. Claims 4, 5, 15 have been amended for clarity. Claim 13 has been amended to more particularly describe the invention. Claims 3 and 14 have been cancelled. Claims 15-17 have been amended to update their dependency. No new matter has been added as a result of this amendment.

The Examiner has objected to the drawings under 37 CFR §1.84(p)(5) for failing to include a radial line through the center of the lumen. The specification and claims have been amended to remove this recitation, thereby rendering the objection moot. Favorable reconsideration is respectfully requested.

Applicant respectfully traverses the Examiner's rejection of claims 1-6, 10 and 12-17 under 35 U.S.C. §102(b) as anticipated by Alchas, U.S. Patent No. 5,030,210. In order to anticipate, the cited reference must disclose each and every claimed element. Alchas fails to do so. In particular, claim 1 (and hence claims 2-6, 10 and 12 depending therefrom) requires that the control valve is configured not only to allow a guidewire to pass through the control valve but to provide a substantially fluid tight seal when the guidewire is removed. Alchas does not describe this feature.

Rather, Alchas describes a valve assembly that is intended and thus configured to readily open in response to pressure differences between an inside of the valve and an outside of the valve. As discussed, for example, at column 3, lines 24-29 of Alchas, this reference is directed to a valve assembly that can readily open in response to medication being fed into the catheter at a pressure greater than blood pressure in order to introduce the medication into the bloodstream. Alternatively, the valve assembly will open in response to a reduced pressure within the catheter in order to obtain a blood sample. Indeed, Alchas describes a valve that is designed to open in response to any pressure differential and thus cannot be considered as capable of providing a fluid tight seal.

Alchas does not describe a control valve that is configured to provide a fluid tight seal when no guidewire is inserted therethrough. While it is conceivable that a guidewire could physically be inserted into Alchas' valve assembly, and subsequently removed, Alchas does not

describe a control valve that is configured to provide a substantially fluid tight seal when such a guidewire is removed. Therefore, claim 1 is patentable over Alchas. Claims 2-6, 10 and 12 depend from claim 1 and add additional limitations and thus are similarly patentable over Alchas.

With respect to independent claim 13 (and hence claims 14-17 depending therefrom), Applicant notes that this claim requires that the polymer sheath disposed over the guidewire port be configured to permit guidewire access through the guidewire port via a passage in the polymer sheath while remaining substantially fluid tight in use when no guidewire is present within the passage. As discussed above with respect to claim 1, Alchas describes a control valve that is configured to open in response to any pressure differential between the inside of the catheter and the outside of the catheter. Thus, one of ordinary skill in the art would not interpret Alchas as describing a polymer sheath having a passage that is configured to remain fluid tight in use. Therefore, claim 13 is patentable over Alchas. Claims 14-17 depend from claim 13 and add additional limitations and thus are likewise patentable over Alchas. Favorable reconsideration is respectfully requested.

Applicant respectfully traverses the Examiner's rejection of claims 1-6, 10 and 12-20 under 35 U.S.C. §102(b) as anticipated by Friedman, U.S. Patent No. 1,719,428. In order to anticipate, the cited reference must disclose each and every claimed element. Friedman fails to do so. In particular, the claimed invention requires that the control valve is configured not only to allow a guidewire to pass through the control valve but to provide a substantially fluid tight seal when the guidewire is removed. Friedman does not describe this feature.

Rather, Friedman is directed to a mechanically dilated vaginal syringe having a fountain head that is apparently intended to permit a spray of water when the dilators covering the fountain head are opened via a twisting action. While it may physically be possible to insert a guidewire into Friedman's syringe, perhaps through an opening formed between adjacent dilators when said dilators are in an open position and then into one of the spray apertures present within the fountain head, this is not equivalent to the claimed invention.

Claim 1 (and thus claims 2-6, 10 and 12 depending therefrom) requires a control valve that is configured to provide a substantially fluid tight seal when the guidewire is removed. Even if one of Friedman's spray apertures is considered to be a guidewire port and Friedman's dilators

are considered to be a control valve (points emphatically not conceded by Applicant), simply removing the guide does not permit the dilators to return to their closed position and thus allegedly provide a fluid tight seal. Rather, Friedman discloses that the dilators are moved to their closed position by rotating an inner body portion with respect to an outer body portion.

Thus, Friedman cannot be considered as disclosing the claimed control valve that is configured to provide a substantially fluid tight seal when the guidewire is removed. One of ordinary skill in the art, having read the instant specification and reviewed the instant drawings, would recognize that the control valve described therein is configured to close together when the guidewire is removed, i.e., it is the guidewire that temporarily holds the control valve open and hence removal of the guidewire causes the control valve to close and thereby provide at least a substantially fluid-tight seal.

Friedman does not disclose each and every claimed element. Therefore, claim 1 is patentable over Friedman. Claims 2-6, 10 and 12 depend from claim 1 and add additional limitations and thus are similarly patentable over Friedman.

With respect to claim 13 (and hence claims 14-17 depend therefrom), Applicant notes that this claim requires that the polymer sheath disposed over the guidewire port be configured to permit guidewire access through the guidewire port via a passage in the polymer sheath while remaining substantially fluid tight in use when no guidewire is present within the passage. When Friedman's vaginal syringe is in use, no guidewire is present or used. When Friedman's vaginal syringe is in use, the dilators are opened in order to expose the fountain head so that water can be sprayed from the fountain head. Friedman cannot be interpreted as disclosing a polymer sheath having a passage that is configured to remain fluid tight in use. Therefore, claim 13 is patentable over Friedman. Claims 14-17 depend from claim 13 and add additional limitations and thus are likewise patentable over Friedman.

With respect to claim 18 (and claims 19-20 depending therefrom), Applicant notes that this is a method claim requiring specific method steps. Friedman does not disclose the claimed specific method steps. As noted above, it may be physically possible to insert a guidewire into Friedman's vaginal syringe. However, this does not anticipate the claimed invention.

Claim 18 requires a step of advancing a guidewire sheath through a control valve and through a guidewire port. Friedman describes neither a guidewire sheath nor a method step of

advancing it through a control valve and thus through a guidewire port. The claim further requires advancing a guidewire through the guidewire sheath. Friedman describes neither a guidewire nor a method step of advancing it through a guidewire sheath. The claim further requires a step of advancing a microcatheter over the guidewire to a treatment site. Given the intended use of Friedman's vaginal syringe, it is unlikely that one of skill in the art would interpret Friedman as disclosing this method step. As discussed above, Friedman cannot be considered as describing removal of the guidewire in order to close the guidewire port.

Thus, Friedman is silent as to disclosing the method steps outlined in claim 18. Claims 19 and 20 depend from claim 18 and add additional limitations. Therefore, claims 18-20 are patentable over Friedman. Favorable reconsideration is respectfully requested

Applicant respectfully traverses the Examiner's rejection of claims 1, 6, 7, 10 and 12-17 under 35 U.S.C. §102(b) as anticipated by Yurek et al., U.S. Patent No. 5,690,644. In order to anticipate, the cited reference must disclose each and every claimed element. Yurek et al. fail to do so.

In particular, claim 1 (and hence claims 6, 7 and 10-12 depending therefrom) requires that the control valve is configured such that fluid pressure within the lumen biases the control valve to assist in forming a substantially fluid tight seal. As this limitation was originally found in claim 3, the rejection has been rendered moot with respect to independent claim 1 and dependent claims 6, 7 and 10-12.

With respect to claim 13 (and hence claims 14-17 depending therefrom), the claimed invention requires that the passage include an angled slit that extends radially through the polymer sheath at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath. This can be seen, for example, in an illustrative but non-limiting reference to Figure 7, which shows a dimension d3 (slit depth) that is greater than a dimension d4 (polymer thickness). Yurek et al. do not disclose such a slit.

Rather, Yurek et al. disclose an axial slit 53 (as cited by the Examiner). While the disclosure indicates that the axial slit 53 may be self-closing as a result of the resiliency of the polymer used to form the outer catheter 20, the reference is silent as to angling the axial slit 53. Indeed, the best view is Figure 5 of Yurek et al., where it can be seen that Yurek et al. disclose

an axial slot that is not angled, but rather extends radially through the polymer layer such that the slot has a depth equal to that of the polymer layer.

Yurek et al do not disclose each and every claimed element. Therefore, claim 13 is patentable over Yurek et al. Claims 14-17 depend from claim 13 and add additional limitations and thus are similarly patentable. Favorable reconsideration is respectfully requested.

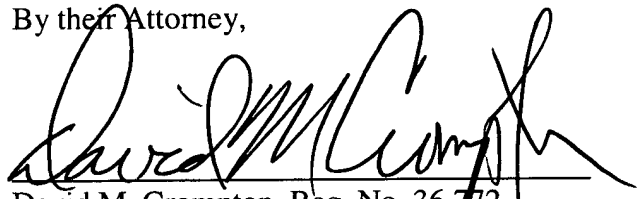
Applicant respectfully traverses the Examiner's rejection of claims 8, 9 and 11 under 35 U.S.C. §103(a) as unpatentable over Yurek et al., U.S. Patent No. 5,690,644, Friedman, U.S. Patent No. 1,719,428, and Alchas, U.S. Patent No. 5,030,210. Yurek et al., Friedman and Alchas have each been distinguished above as failing to disclose the invention of claim 1. Claims 8, 9 and 11 each depend from, and further limit, claim 1. Thus, claims 8, 9 and 11 likewise are patentable over the cited combination of references. Favorable reconsideration is respectfully requested.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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Attachment: Two Replacement Drawing Sheets

Amendments to the Drawings

The attached sheet of drawings includes changes to Figures 5, 7 and 8. These sheets, which include Figures 4, 5 and 6 and Figures 7 and 8, respectively, replace the original sheets including Figures 4, 5, 6, 7 and 8. In Figures 5, 7 and 8, reference number 46 has been changed to reference number 44, for consistency.

Attachment: Two Replacement Drawing Sheets